EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
(HOUSTON DIVISION)

GAYATHRI MURTHY, Plaintiff,	§ § §	
v.	§	CASE NO. 4:11-cv-00105-KPE
ABBOTT LABORATORIES, Defendant.	§ § §	

PLAINTIFF'S SUPPLEMENTAL MEMORANDUM IN SUPPORT OF RESPONSE TO MOTION TO DISMISS

As Ordered by the Court [Doc 27], Plaintiff files this Supplemental Memorandum elaborating on the following sentence in her initial Memorandum:

> Because § 82.007 is a defensive statutory presumption, there is no requirement for a plaintiff to anticipate and negate it in her Complaint.

Hopefully, we will discern and address the Court's concerns.[1]

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[1] Although the sentence appears in the section dealing with preemption, we did not interpret the Court's Order as calling for any further briefing on federal preemption. The preemption issue will raise its head, if, and only if, Abbott contends (as other pharmaceutical companies have done) that subsection § 82.007(b) is preempted by *Buckman*, such that the plaintiff may not use evidence of information withheld from the FDA to rebut the statutory presumption. *See e.g., Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 274 (5th Cir. 2010), in which the drug company argued that "federal law preempts the exception in § 82.007(b)(1), which permits a plaintiff to rebut the presumption by presenting evidence that the defendant withheld from or misrepresented to the United States Food and Drug Administration ("FDA") material and relevant required information," but the court never reached the issue.

Our argument, *if and when Abbott takes such a position*, will be that – if Abbott is right – then the *entire statute* is preempted. Counsel have briefed this issue before. However, the briefing is somewhat lengthy and we would not want to burden the Court with same in the current hypothetical state of the record.

Procedurally, the Plaintiff must file a Complaint containing a "short and plain statement" that shows that she is "entitled to relief." Rule 8, FED. R. CIV. P. The recent jurisprudential gloss on this Rule, *i.e.,* the "plausibility" language of *Twombley* and *Iqbal,*[2] and their progeny was addressed in our initial Memorandum.

Although the case law is sparse, it is clear that the "general rule" of pleading is that there is no requirement to "anticipate a defense." *See e.g., Gomez v. Toledo,* 446 U.S. 635, 640, (1980)("We see no basis for imposing on the plaintiff an obligation to anticipate such a defense [qualified immunity] by stating in his complaint that the defendant acted in bad faith.").[3] Eighteen years later, the High Court reaffirmed *Gomez* and wrote about the perils of judicial decisions that, in effect, "change the Federal Rules governing pleading by requiring the plaintiff to anticipate [the immunity] defense." C*rawford-El v. Britton,* 523 U.S. 574, 595 (1998).

The defendant's Answer "must affirmatively state any . . . affirmative defense." Rule 8(c), FED. R. CIV. P. At this point, Abbott has not yet filed an Answer in this

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[2] *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007); *Ashcroft v. Iqbal*, 556 U.S. ——, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009).

[3] In subsequent § 1983 cases the Fifth Circuit has held that courts can "stand by our insistence that complaints plead more than conclusions, and that a plaintiff can, at the pleading stage, be required to *engage the affirmative defense* of qualified immunity when invoked." *Schultea v. Wood,* 47 F.3d 1427, 1430 (5th Cir. 1995). However, even here, the plaintiff is not required to anticipate the affirmative defense until it has been "invoked" by an answer and the court has decided to require further pleading. *See e.g., Detro v. Roemer,* 732 F. Supp. 673, 675 (E.D. La. 1990)("Because qualified immunity is an affirmative defense which must be pleaded, the plaintiff need not anticipate the defense in his complaint.").

case. However, pharmaceutical companies typically assert § 82.007 as an affirmative defense, so it is likely that Abbott will do so as well.

However, to be technically precise, the statute is *not* an affirmative defense. A careful examination of the products liability portions of the Texas Civil Practice and Remedies Code illustrates the fact that the Texas Legislature knows the difference between affirmative defenses, burdens of proof, and evidentiary presumptions. Section 82.004, by its wording, "a manufacturer or seller shall not be liable," does provide an affirmative defense for certain "inherently unsafe products." Section 82.005, dealing with design defects, places the burden of proof by legislative fiat: "the burden is on the claimant to prove . . ."

By contrast, § 82.007 (and its parallel § 82.008) specifically provides for a rebuttable *evidentiary presumption*: "there is a rebuttable presumption that . . ." Indeed, the statute even sets forth some[4] of the evidence that might be used to rebut the presumption.

As noted in our original Memorandum, to counsel's knowledge, the only case that actually discusses the practical application of § 82.007 is *Ackermann v. Wyeth Pharmaceuticals*, 471 F. Supp. 2d 739, 749 (E.D. Tex. 2006) aff'd, 526 F.3d 203 (5th

[4] At this point, the paucity of judicial construction of § 82.007 leaves open the question of whether the list of evidence that could be used to rebut the presumption is *exclusive*, or merely illustrative.

Cir. 2008), which held that "once *evidence* contradicting the presumption has been offered, the presumption disappears and is not weighed or treated as evidence."

Although we were not required to "anticipate" this defensive reliance on the statute, our pleadings do provide some guidance regarding the potential applicability of § 82.007 in the first place. For example, because § 82.007 does not apply to an "indication not approved" by the FDA, it is highly questionable whether it applies at all to patients enrolled in any kind of clinical trial. *See* ¶ 13 of Amended Complaint. Additionally, as plead in our Response Memorandum, there are very plausible allegations that not *all* of the information given to Ms. Murthy was FDA approved. *E.g.,* the videotape produced by the drug company. *Id.* at ¶ 20-21. *See e.g., Centocor, Inc. v. Hamilton,* 310 S.W.3d 476, 522 (Tex. App. 2010)*(*"Moreover, it is not clear that this statute was intended to cover something other than a package insert, which accompanies a prescription drug 'in its distribution."), *appeal pending*.

Once the evidentiary facts are all marshaled via discovery, the Court can then address the applicability *vel non* of § 82.007, to this case. If, as in *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 682 F. Supp. 2d 662, 675 (N.D. Tex. 2010), the Court finds (a) that the statute applies, and (b) that there is no evidence to rebut the statutory presumption, then at that time summary judgment might be appropriate. But Abbott's reliance on § 82.007 for dismissal purposes at the pleadings stage is entirely without basis in law or in fact.

Respectfully submitted,

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Certificate of Service

I certify that on this 31st day of August 2011, Plaintiff's Supplemental Memorandum in Support of Response to Motion to Dismiss has been electronically filed with the Clerk using the CM/ECF system, which will automatically send email notifications of such filing to the following attorneys of record:

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